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09/691,957	10/18/2000	Samuel Benjamin Schaevitz	ACBI.049.00US	5382

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EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/30/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/691,957

Applicant(s)

SCHAEVITZ ET AL.

Examiner

Elizabeth Quan

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. "Relevant Art" on lines 5-9 of page 2 has not been considered and may be omitted from the specification.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show line 1a-1a in FIG. 1 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The abstract of the disclosure is objected to because the sentence on lines 8 and 9 of page 11 is ambiguous. A possible modification includes: The collars are protrusions extending from the surface of the devices, and the internal walls of the collars generally align with the internal walls of the microstructure. Correction is required. See MPEP § 608.01(b).

Art Unit: 1743

4. The disclosure is objected to because of the following informalities: The sentence on lines 21 and 22 of page 1 is ambiguous. A possible modification includes: The problem encountered with very small volumes is evaporation. The term "adventitious" on lines 27-29 renders ambiguity in the process of pressurization. The sentence on lines 31 and 32 of page 1 could provide a more detailed explanation to what part "around a part" refers to. The term "injurious" in the sentence on lines 1-3 of page 2 could be explained in more detail as to what and why these "injurious events" occur with open ports of a microfluidic device. The word "there" may be inserted between "which" and "are" on line 6 of page 3. A space may be incorporated between "side" and "using" of "sideusing" on lines 9 of page 3. A possible modification for the sentence on lines 18 and 19 of page 3 includes: The sealing cover or lid will be a film, which forms a seal about the collar to at least substantially inhibit fluid flow from the reservoir. The sentence on lines 24-27 of page 3 is ambiguous. "m" should be inserted after the Greek symbol to appropriately represent micron on line 3 of page 4. A space between "may" and "be" of "maybe" may be incorporated on line 17 of page 4. The sentence on lines 28-30 of page 4 is ambiguous. The term "addition polymers" on line 28 of page 5 is not known to one having ordinary skill in the art. A more detailed description is required for understanding. "so" may be omitted between "made" and "by" on line 30 page 5. The sentence on lines 4-6 of page 8 is ambiguous with "avoiding trapping." The sentence on lines 25-28 of page 8 is unclear. Appropriate correction is required.

#### *Claim Objections*

5. Claim 12 is objected to because of the following informalities: "lead" should be replaced by "lid." Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,273,718 to Skold et al.

Referring to claim 1, Skold et al. shows a substrate (35) of planar surface with openings surrounded by a collar (see FIGS 2-4). Therefore, Skold et al. includes all the limitations of claim 1.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1743

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,273,718 to Skold et al.

Referring to claim 2, Skold et al. do not disclose the thickness of the collar.

According to *In re Aller*, the discovery of an optimum or workable range is characterized as routine experimentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the thickness of the collar as necessary to prevent contamination between wells and increase the effective volume of the wells. Therefore, the claimed device is not patentably distinct from prior art device based on the thickness of the collar.

Referring to claim 6, Skold et al. shows a substrate (35) of planar surface with openings surrounded by a collar (see FIGS 2-4). Skold et al. do not disclose the volumes of the reservoirs and the height and thickness of the collars. Applying the decision made by the Federal Circuit in *Gardner v. TEC Systems, Inc.*, the volume of the reservoirs would not affect the performance of the claimed device respective to prior art device. It would have been obvious to one having ordinary skill in the art at the time the invention

Art Unit: 1743

was made to modify the volume of the reservoirs as necessary to process the desired volume of samples. Furthermore, according to In re Aller, the discovery of an optimum or workable range is characterized as routine experimentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the height and thickness of the collar as necessary to prevent contamination between wells and increase the effective volume of the reservoirs. Therefore, the claimed device is not patentably distinct from prior art device based on the height and thickness of the collar as well as the volume of the reservoir.

12. Claims 3-5 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,273,718 to Skold et al. as applied to claims <sup>2 and 6</sup>1, and in further view of U.S. Patent No. 6,251,343 to Dubrow et al.

Referring to claims 3-5, Skold et al. do not disclose the materials used in the apparatus. Dubrow et al. discloses the substrate and cover layer injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12). To provide an effective barrier between neighboring reservoirs the upper surface of the cover layer may be coated with a polymer (see COL. 7, lines 62-67; COL. 8, lines 1-3). The cover layer may be attached to the body structure of the device by adhesive bonding, preferably using U.V. curable adhesives for tight sealing against evaporation (see COL. 9, lines 13-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Skold et al. to provide a plastic molded microfluidic

Art Unit: 1743

device including a conformable lid with adhesive coating to provide an effective barrier between reservoirs and better sealing between the cover plate and body structure to prevent evaporation.

Referring to claim 7, Skold et al. do not disclose channels. Dubrow et al. discloses ports in the body structure, which are in fluid communication with one or more channels in the first channel network (see FIGS. 2A-2F and 3B; ABSTRACT). While Dubrow et al. do not explicitly state why the reservoirs are in communication through a channel, it appears the applied pressure and voltage gradients are better dispersed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate reservoirs in communication with channels of Dubrow et al. to the apparatus of Skold et al. for better dispersion of applied pressure and voltage gradients.

Referring to claims 8-11, Skold et al. do not disclose the materials used in the apparatus. Dubrow et al. discloses the substrate and cover layer injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12). To provide an effective barrier between neighboring reservoirs the upper surface of the cover layer may be coated with a polymer (see COL. 7, lines 62-67; COL. 8, lines 1-3). The cover layer may be attached to the body structure of the device by adhesive bonding, preferably using U.V. curable adhesives for tight sealing against evaporation (see COL. 9, lines 13-24). A flexible gasket may optionally be placed between the upper surface of the body structure and



Art Unit: 1743

lower surface of the cover layer (see COL. 9, lines 26-29). Additionally, the reservoirs spaced according to conventional multi-well plates, such as a 96-well, 384-well, or 1536-well (see COL. 9, lines 53-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Skold et al. to provide a plastic molded microfluidic device including a conformable lid with adhesive coating to provide an effective barrier between reservoirs and better sealing between the cover plate and body structure to prevent evaporation and position reservoirs to conveniently match existing multi-well plates.

Referring to claims 12-14, Skold et al. do not disclose a compliant lid nor an electrokinetic device. Fluid volumes are introduced into the ports (see COL. 7, lines 15-23). Dubrow et al. discloses the substrate and cover layer injection molded polymeric or plastic part from a variety of materials including an acrylic polymer such as polymethylmethacrylate (PMMA) (see COL. 3, lines 61-67; COL. 4, lines 1-7; COL. 8, lines 66 and 67; COL. 9, lines 1-12). To provide an effective barrier between neighboring reservoirs the upper surface of the cover layer may be coated with a polymer (see COL. 7, lines 62-67; COL. 8, lines 1-3). The cover layer may be attached to the body structure of the device by adhesive bonding, preferably using U.V. curable adhesives for tight sealing against evaporation (see COL. 9, lines 13-24). A flexible gasket may optionally be placed between the upper surface of the body structure and lower surface of the cover layer (see COL. 9, lines 26-29). Further, the microfluidic device uses an electrokinetic material transport system, which create virtual valves including no mechanical or moving parts, to direct and transport materials through the

Art Unit: 1743

channels of the device (see COL. 4, lines 56-59; COL. 6, lines 22-24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a compliant/adhesive lid with a gasket for effective sealing against evaporation and make use of an electrokinetic material transport system to induce virtual valves with no mechanical or moving parts to the apparatus of Skold et al.

*Conclusion*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1193.

Elizabeth Quan  
Examiner  
Art Unit 1743

eq  
January 27, 2002

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700

Application/Control Number: 09/691,957

Art Unit: 1743

Page 10